

REMARKS

A. Status of the Claims

Claims 1-10 and 12-21 are pending in the application, with claims 9, 10, 12-19 and 21 withdrawn. Claims 1-8 and 20 are under consideration and stand rejected, variously, under 35 U.S.C. §112, first paragraph (written description and enablement) and 35 U.S.C. §103. The specific grounds for rejection, along with applicants' response thereto, are set out in detail below.

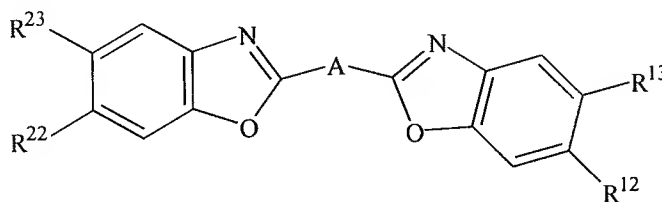
B. Objections

Claims 2, 4, 5 and 7 are objected to for informalities. Amendments are provided addressing the examiner's concerns.

C. Further Response to Restriction Requirement

Applicants submit the following additional traversal of the restriction requirement. It is believed that the examiner should not have made final the restriction given the new reliance of the examiner Belfield. Given the fact that a new reference is used to support the restriction, applicant has the right to have additional arguments considered showing that the claims relate to a single general inventive concept (without filing a petition).

According to the examiner, there is no technical relationship among the three general structures claimed in claim 1 involving one or more of the same or corresponding special technical features ("STF") (*see* Rule 13.2 PCT). However, the STF that the examiner identified at page 3 of the office action is not correct. The true STF is the following:



wherein A is a cyclic hydrocarbon group, optionally aromatic or heteroaromatic and optionally substituted, and the R groups represent hydrocarbon substituents that may form a cyclic structure, *e.g.*, a 9,9-dipropylindeno[3,2-f]-2-benzoxazolyl group.

The special situation involving the so-called Markush practice is also governed by Rule 13.2 PCT. In case of a claim defining (chemical or non-chemical) alternatives, *i.e.*, a so-called “Markush-grouping,” unity of invention should be considered to be present ***if the alternatives are of a similar nature and can fairly be substituted for one another***. See MPEP § 1850 III.B, which states that:

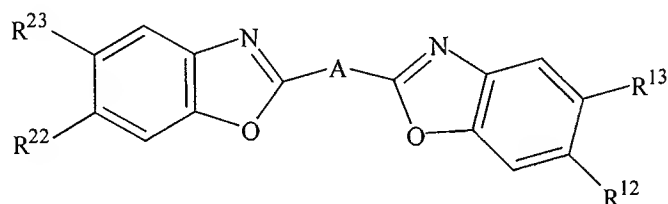
When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity; and
- (B) (1) A common structure is present, *i.e.*, a significant structural element is shared by all of the alternatives;

In paragraph (B)(1), above, the words “significant structural element is shared by all of the alternatives” refer to cases where ***the compounds share a common chemical structure which occupies a large portion of their structures***, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, ***and the common structure is essential to the common property or activity***. The structural element may be a single component or a combination of individual components linked together.

It should also be noted that MPEP § 1850 III.B does not require the common significant structural element to be novel and inventive over the prior art. The sole decisive criterions are that the alternatives all be patentable and of a similar nature. Markush practice is a special situation where the common significant structural element is not required to define a contribution over the prior art.

In the present case, the three structures claimed in claim 1 have a common activity, since the compounds are useful as UV filters that do not absorb in the visible spectrum. Further, the claimed Markush alternatives are patentable over the prior art references, as evidenced by the arguments provided in response to the obviousness rejection. Finally, the three alternative structures of claim 1 share a significant common chemical structure which occupies a large portion of their structures, *i.e.*, the following common non-variable core:



wherein A and the R groups are as defined above. Thus, the three formulae of instant claim 1 can be regarded as being of a similar nature and can fairly be substituted for one another. This confirms that restriction between Groups I-V is improper as there is a technical relationship among all inventions of the present application involving the same (or corresponding for claims 17-19, 21) special technical feature as depicted on the above drawing.

In view of the above, applicants request withdrawal of the Restriction Requirement between Groups I-V, and examination of all of the corresponding in the present case is requested.

C. Rejections Under 35 U.S.C. §112, First Paragraph

I. Written Description

According to the examiner, the generic nature of applicants' claims 1-3, 6, 8 and 20 is such that they lack an adequate written description. More specifically, it is the examiner's position that the specification provides insufficient examples of specific compounds falling

within the scope of these claims, as well as insufficient evidence regarding structure-function relationships amongst the many compounds covered. Applicants disagree.

The examiner's first cites to *In re Gosteli* for the proposition that two chemical compounds cannot support a genus. No such rule of law is devisable from that case, or any other relevant precedent. Rather, it is the application of *all* the facts of a *particular* application that determines whether the written description is satisfied. Moreover, the written description holding in the *Gosteli* case hardly fits the facts here: "In this case, the PTO has met that burden by pointing out a number of differences between what is disclosed in the Luxembourg priority application and what is claimed in Gosteli's United States application. Gosteli does not dispute that additional subject matter is present in the United States application. Accordingly, the Board's findings are not clearly erroneous." Here, there is only *one* disclosure, not *two*. Neither the Board or the Federal Circuit questioned Gosteli's ability to advance their claims, only whether they received benefit of priority to the earlier Luxembourg priority filing.

Turning to the examiner's fundamental argument – that there is insufficient description because only certain compounds have been "reduced to practice" – applicants submit that it too is faulty. There is no requirement under §112, first paragraph for "reduction to practice." Rather, the test is whether one of skill in the art would believe that applicants' were in "possession" of the invention. The courts have defined possession broadly:

Possession may be shown in a variety of ways including description of an actual reduction to practice, *or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.* See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

MPEP § 2163.02 (emphasis added). In any event, applicants point out that X¹ and X² have been limited to O, thereby substantially reducing the encompassed subject matter.

There is also a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”). However, the issue of a lack of adequate written description may arise even for an original claim, but only when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention. The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. Such is clearly not the case here, nor has the examiner even suggested such.

Finally, the examiner’s reliance on *Fujikawa v. Wattanasin* is badly misplaced. The issue at bar was *not* whether an original claim was supported, but whether a proposed *new* claim to a subgenus was described. As stated by the court itself, “In finding that Wattanasin’s disclosure failed to sufficiently describe *the proposed sub-genus*, the Board again recognized that the compounds of the proposed count were not Wattanasin’s preferred, and that *his application contained no blazemarks as to what compounds, other than those disclosed as preferred, might be of special interest*. In the absence of such blazemarks, simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as *to particular species or sub-genuses*”. Nothing could be further from the case here. The claims being rejected are

original, and the claims as amended herein, which simply limit X^1 and X^2 to O, are clearly identified.

In sum, the examiner has done nothing more than point out whether the experimental evidence provided by applicants diverges from the claims. This is inadequate to make out a rejection for lack of written description under §112, first paragraph. Given that the examiner has not satisfied the PTO's burden in making out a *prima facie* case in support of the rejection, applicants request both reconsideration and withdrawal thereof.

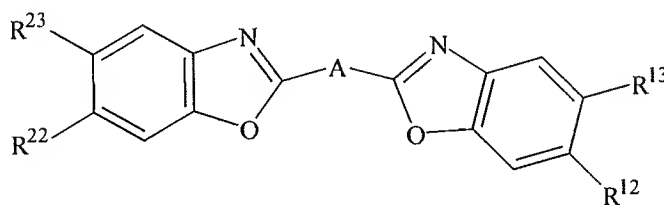
II. Enablement

Claims 1-3, 6, 8 and 20 are also rejected as allegedly lacking an enabling disclosure. In essence, the examiner's attack is two-fold. First, it is argued that applicants have not synthesized enough compounds falling within the scope of the claims to demonstrate that experimentation be required to make all of the encompassed compounds would not be undue. Second, it is alleged that the invention falls within the realm of an "unpredictable and undeveloped" art, and thus is somehow *per se* non-enabled without more experimental evidence. Applicants disagree.

As set forth in *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244, 68 USPQ 2d 1280, 1287 (Fed. Cir. 2003) that "the applicant's specification must enable one of ordinary skill in the art to practice the full scope of the claimed invention. *Wright*, 999 F.2d at 1561. That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art." The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, at 736-737 (Fed. Cir. 1988).

Availability of Starting Materials. A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the present case, precursors of the claimed compounds (*e.g.*, dicarboxy compounds and ring-substituted or unsubstituted ortho-aminophenols, ortho-diamines or ortho-aminothiophenols; Specification at pages 16, 25) are well known in the art. They are available, either commercially (*e.g.*, 1,4-dicarboxy anisole; Specification at page 16) or through chemical synthesis involving standard reactions (*e.g.*, the dicarboxy compound prepared in three steps in the specification at page 24). The reactivity of these compounds is also well-known. The selection of adequate chemical precursors to the claimed compounds does not require knowledge beyond the general knowledge available to those of skill in the art. Those skilled in the art do not require inventive skill to select appropriate precursors.

Breadth of the Claims. The general structure of the claimed compounds is rather well-defined and the claimed genus does not exhibit substantial variance, contrary to the examiner's contentions at pages 10 and 12. All the claimed compounds share a significant common chemical structure which occupies a large portion of their structures, *i.e.*, the following common non-variable core:



wherein A is a cyclic hydrocarbon group, optionally aromatic or heteroaromatic and optionally substituted, and the R groups represent hydrocarbon substituents that may form a cyclic structure, *e.g.*, a 9,9-dipropylindeno[3,2-f]-2-benzoxazolyl group.

State of the Prior Art. As can be seen from Belfield (Scheme 1, page 4636), two additional alternative synthetic routes are available to prepare the claimed compounds, in addition to the route disclosed in the present application: the use of an aldehyde precursor in a cyclocondensation reaction, or a palladium catalyzed coupling using aryl bromides and aryltributylstannyl precursors (Stille coupling). Implementing the above reactions does not exceed the ordinary skill and knowledge level of those skilled in the art.

This establishes a reasonable level of predictability in the art for preparing of the claimed compounds, *e.g.*, the synthetic methods of Belfield for 2-arylbenzothioazole compounds ($X = S$), which could be useful for preparing 2-substituted benzoxazole analogs ($X = O$). Therefore, it cannot be said that the relevant art is “undeveloped.” Moreover, the fact that preparation of the claimed compounds involves well-established synthetic routes is evidenced in numerous reference books such as *The Chemistry of Heterocyclic Compounds, Volume 60, Oxazoles: Synthesis, Reactions, and Spectroscopy* (Wiley, New York, 2003, David C. Palmer, Editor). Thus, 2-arylbenzoxazoles belong to a category of compounds that are well-known in the state of the art and easily synthesizable.

Level of Skill in the Art. It can be concluded from the previous section that there was a high level of skill in the art at the time the application was filed, and all of the methods needed to practice the invention were well known (*In re Wands*, 858 F.2d 731, at 740, 8 USPQ2d 1400, at 1406 (Fed. Cir. 1988)). In addition, the examiner conceded that the relative skill of those in the art was high (action at page 12). Therefore, the skilled artisan can use the general knowledge available to those of skill in the art to prepare a large variety of non exemplified bis-benzoxazoles without any technical difficulty, since these compounds are classical compounds, the preparation of which is abundantly disclosed in the prior art. Moreover, those skilled in the

art can adjust the conditions for a reaction involving other starting materials than those specifically exemplified without undue burden.

Level of Predictability. As discussed above, the level of predictability in the art related to the nature of the disputed groups is reasonable. There is no unpredictability in performance of some substituents other than those specifically exemplified. Indeed, proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. MPEP § 2164.02. In this regard, the examiner has not stated why one would not expect to be able to extrapolate the examples across the entire scope of the claims. Adequate reasons have not been advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation. Stated another way, the examiner does not raise any well-founded reason, any reason which would be supported specifically by a published document, demonstrating that there are well-founded reasons for believing that the skilled person would be unable, on the basis of the information given in the application as filed, to put the claimed invention into practice over the whole of the field claimed, *i.e.*, to prepare the compounds having the challenged substituents. To the contrary, the examiner conceded that the relative skill of those in the art was high (action at page 12).

The claimed compounds exhibit common properties, a common utility, and share substantial structural features which are essential to that utility. Indeed, these compounds all are bis-benzoxazoles compounds connected through a central ring. Thus, there is no well-founded reason for believing that other Y, R², R³, R¹², R¹³, R²² and R²³ groups than those specifically exemplified would not work. In particular, the exact nature of Y, R², R³, R¹², R¹³ and R²² is only a secondary parameter. For example, the examiner has conceded that adjacent members of an alkyl chain are adjacent homologs, *i.e.*, would be expected to have the same properties.

Working Examples/Guidance Provided by Applicants. Concerning the amount of direction provided by the inventor, applicant has disclosed with full details one general route to the claimed compounds by way of two examples. This number of working examples is sufficient for a full enablement over the whole of the field claimed. Since only an enabling disclosure is required, Applicant need not describe all actual embodiments, *i.e.*, the multitude number of combinations encompassed by the claims (see MPEP § 2164.02). Examples 1 and 2 are representative of the three structures claimed in claim 1. Example 1 is related to families I and III, while example 2 is related to family II. As already discussed, the disclosed synthetic route to the claimed compounds allows the preparation of the claimed compounds, whatever the nature of groups Z^1 , R^2 , R^3 , R^{12} , R^{13} and R^{22} .

It should be kept in mind that a patent need not teach, and preferably omits, what is well known in the art. MPEP § 2164.01 (“[A] specification need not disclose what is well known in the art.” *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997)). Adequate guidance is also provided by the patents cited in the present disclosure (U.S. Patent 5,587,112 and U.S. Patent 5,298,189), which confirm that the chemistry of bis-benzoxazoles connected through a central ring, such as phenylene, was well known at the filing date. Finally, it is stated in MPEP § 2164.03 that the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). These *Wands* factors have been discussed favorably above.

Quantity of Experimentation. According to the examiner, *the synthesis of all possible variations* of the claimed compounds would require much experimentation. This is true, since the amount of experimentation is proportional to the number of compounds to be synthesized. However, what is required is that the quantity of experimentation needed to achieve the

objectives be reasonable. It is not required that a limited number of experiments be necessary to make **all** of the combinations encompassed by the claims. The experimentation needed to synthesize all the compounds encompassed by the claims is reasonable and requires a few synthetic steps per compound.

Regardless, *In re Wands* explains that a considerable amount of experimentation is permissible, if it is **merely routine**, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. In the present situation, only routine experimentation is needed, and one general route to the claimed compounds has been disclosed, while alternative routes are disclosed in the literature. Undue experimentation is thus not required.

Conclusion. The use of the claimed compounds for producing optical articles such as ophthalmic lenses that exhibit satisfactory absorption characteristics in the UV and visible ranges is enabled and correlates with the entire scope of the claims, which precludes a rejection for nonenablement based on how to use (MPEP § 2164.01(c)). MPEP § 2164.01(b) further states that as long as the specification discloses at least one method for **making and using** the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. §112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

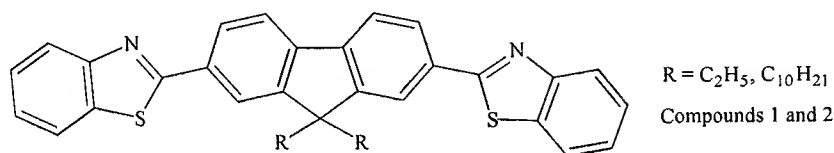
Those skilled in the art are consequently able to **produce and use** the claimed compounds through the whole subject matter as claimed in claim 1, so that it should be recognized that the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

D. Rejection Under 35 U.S.C. §103

Claims 1 and 8 are rejected as allegedly being obvious over either of Belfield or Yang in view of Patani, the latter being cited only to demonstrate that some group substitutions are obvious. Applicants disagree.

I. **Belfield**

Belfield discloses compounds 1 and 2 having the following formula:



The structural differences between amended claim 1 (particularly Family II) and Belfield are the presence of groups Z¹, R²², R²³, R¹² and R¹³, the nature of the alkyl groups on the 9H-fluorene group and a benzoxazole ring instead of a benzothiazole ring. The structural differences between amended claim 8 and Belfield are the presence of the Z¹ group, the ethyl groups, the nature of the alkyl groups on the 9H-fluorene group and a benzoxazole ring instead of a benzothiazole ring.

Since claim 7 was not rejected by the examiner over these references, the recitation of benzoxazole rings in the claims presented above should be sufficient to distinguish from Belfield, which only discloses compounds having benzothiazole rings (X¹, X² = S).

Turning to Patani, the examiner relies on this reference to assert that H/OH and H/alkyl groups substitutions are obvious. However, it can be seen in Figure 37 at page 3159 of the reference that O/S group substitution in the X-azole series does *not* lead to homolog compounds. Consequently, O/S group substitution in the benz-X-azoles of Family II would not necessarily lead to equivalent compounds. In other words, modifying the sulfur atoms in compounds 1 and 2 of Belfield yields compounds with varying and unpredicted properties. Thus, obviousness will not stand.

II. Yang

Yang discloses polybenzimidazoles having a repeating unit that is similar to Belfield and mainly differ from compounds claimed in Family II of claim 1 by the presence of a benzoxazole ring instead of a benzimidazole ring ($X^1 = X^2 = \text{NH}$). Yang aims at preparing an iodide sensor, while applicants' claimed invention is directed to a UV absorber for polymer materials. These objectives are very different (see page 1 of the present application): "The present invention relates to compounds that absorb ultraviolet light 380 nm to 400 nm range while avoiding absorption in the yellow light range, *i.e.*, 410-420 nm." Yang does not appear relevant, considering that the disclosed polybenzimidazole does not have the required absorption characteristic to be able to be used as a UV absorber for polymer materials. The absorption spectrum at page 374 reveals that Yang's compound still strongly absorbs light between 410 and 420 nm, so that it would not avoid yellowing of the polymer material in which it would be incorporated. Its absorption only becomes negligible above 435-440 nm.

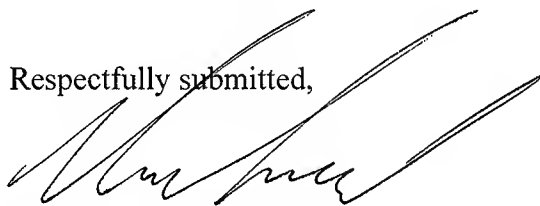
In addition, applicants disagree with the examiner's statement that Yang's compound disclosed at page 375 and compounds of instant claims 1-8 are homologs and bioisosteres. Compounds of instant claims 1-8 are low molecular weight entities, while Yang's compound is a polymer. Accordingly, steric contributions of these compounds are very different. To assert that they are bioisosteres, *i.e.*, that they further have similar biological properties, is still more hazardous. Consequently, Yang's compound does not exhibit a structure that is sufficiently similar to the claimed compounds, and thus MPEP § 2144.08.II.A.4(c) cannot be relied on. There was not a reasonable expectation of success for obtaining an additional compound having similar properties or for the same utility. The skilled person would not expect to obtain similar properties, and, as explained above, applicant's claimed compounds and Yang's compound do not have similar properties.

In conclusion, the presently claimed compounds and those of the reference are not suitable for the same use, which demonstrates the lack of motivation to modify Yang. There simply is no apparent reason to perform the required modifications in the polymer of Yang so as to arrive at the claimed compounds, and there is no teaching in the cited prior art references of how making Yang's compound suitable to be used as a UV absorber for polymer materials. As such, obviousness will not stand.

E. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. Should the examiner have any questions, comments, or suggestions relating to this case, the Examiner is invited to contact the undersigned Applicants' representative at (512) 536-3020.

Respectfully submitted,



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